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PATENT TRADEMARK OFFICE

Patent  
Case No.: 48317US027

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: JAPUNTICH, DANIEL A.  
 Application No.: 09/678579 Group Art Unit: 3761  
 Filed: October 3, 2000 Examiner: Aaron J. Lewis  
 Title: FIBROUS FILTRATION FACE MASK HAVING A NEW  
 UNIDIRECTIONAL FLUID VALVE

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REPLY BRIEF

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| I hereby certify that this correspondence is being facsimile transmitted to the U.S. Patent and Trademark Office on: |                           |
| December 3, 2003   | <i>Susan M. Dacko</i>     |
| Date   | Signed by: Susan M. Dacko |

Dear Sir:

Applicants submit this Reply Brief in response to the Examiner's Answer mailed October 3, 2003. Applicants respectfully dissent from a number of positions taken by the Examiner. Each of the Examiner's positions is reproduced below in quotes, followed by applicants' rebuttal argument.

1. Examiner's Answer at page 3, paragraph bridging pp. 3 and 4

"Simpson et al. disclose the use of the mask in environments which have noxious fumes present; consequently, given the manner of operation of the filtering mask and exhalation valve, in order for it to protect a wearer from noxious fumes, it stands to reason that the exhalation valve remains closed in all physical orientations (i.e. the exhalation valve body is pressed towards the seal surface in an abutting relationship when (during inhalation) fluid is not passing through the orifice (16)) except during user exhalation."

Applicants' Response:

The Examiner is reviewing the Simpson patent from the perspective of the person who has read specification of applicants' invention rather than from the state-of-the-art that existed at the time the Simpson patent was published. Because Simpson does not impose a preload on its flapper valve 13 shown Figure 2 and because Simpson places the valve 12 on the top portion 10f the mask (figure 1) and suggests the use of an antechamber to prevent harmful contaminants

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from leaking into the mask through the exhalation valve, it is clear that the Simpson valve does not remain closed under any orientation of the mask. Thus, although it may be apparent that a person of ordinary skill would want to design a flapper valve that remained closed under all conditions after reading applicants' specification, it certainly was not apparent to Simpson in 1980. While the Examiner may asserts that "it stands to reason" that such a valve would have been created in the Simpson disclosure, the record does not reflect any evidence of this. Indeed, the record reflects the exact opposite. The Examiner's "reasoning" thus does not derive from Simpson but rather is a viewpoint that was arrived at after reading present specification.

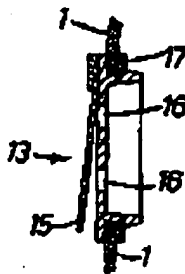
**2. Examiner's Answer at page 7, paragraph bridging pp. 7 and 8**

"Applicant's arguments hinge on speculation of a possibility that valve flap (15) of Simpson et al. might 'droop' away from the valve seat. There is no support in the disclosure of Simpson et al. which forms a basis for such a position."

**Applicants' Response:**

The Examiner has erred in interpreting the scope and content of Simpson. Applicants' arguments do not "hinge on speculation" because there are in fact three particular disclosures that show why the Simpson flap is not pressed towards the seal surface under any orientation of its valve.

Firstly, the construction Simpson valve itself shows that there is no preload or bias placed on the flap:



**FIG. 2.**

As the Board can note, the flap-retaining surfaces is in direct alignment with the seal surface, and there is no other instrument that causes the flap to be pressed towards the seal surface.

Therefore, when the valve is inverted, gravity will act upon flap 15 to force it downward. The

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valve flap — if made from a conventional flap material, which we must assume it is since the patent does not disclose otherwise — will then droop away from the seal surface.

Secondly, Simpson indicates that its valve can leak in the paragraph set forth on page 1, lines 58-64 in the specification:

To prevent inhalation of harmful atmosphere owing to leakage of the or each valve, the valve may be provided with an antechamber so arranged that, if the valve does leak in operation, the wearer inhales previously exhaled breath and not the harmful atmosphere.

This admission of leakage demonstrates that the flap droops away from the seal surface.

Applicants are not aware of any other way in which the flap could leak.

Thirdly, Simpson shows the valve 12 on the top portion of the filtering face piece. In this position, the valve can take advantage of gravity to encourage the flap 15 to remain pressed against the seal surface when a wearer is neither inhaling nor exhaling. If a wearer tips their head downward, however, the advantage of gravity would be lost, and the flap could then droop away from the seal surface.

Previously submitted Affidavits of Dave Castiglione (Exhibit A) and of John Bowers (Exhibit B) both support the position that Simpson's valve could allow for the influx of contaminants because the flap is not pressed against the seal surface when a neutral position. For ease of reference, applicants have reproduced paragraph 9 of the Castiglione Affidavit:

9. That I do not agree with the position taken by the Examiner at the bottom of page 3 of the Office Action. My review of the '516 UK patent application leads me to the conclusion that the valve 13 shown in Figure 2 does not have its flap 15 pressed towards the seal surface in an abutting relationship when the wearer is neither inhaling or exhaling. The '516 application reveals two distinctly different valves: a flap valve 13 as shown in Figure 2; and a diaphragm valve 14 as shown in Figure 3. These flaps have distinctly different constructions and operate differently. The [flapper] valve shown in Figure 2 has a flat seal surface. The mounting of the flap 15 to the seal surface at the top or fixed portion of the flap does not show a preload on the flap 15. There is nothing that can be discerned from Figure 2 or from the specification that would indicate that the flap is pressed towards the seal surface in its neutral position. And because Figure 3 shows a flap 18 resting upon the seal surface in the flap's neutral position while Figure 2 shows the flap 15 dangling away from the seal surface in an apparent neutral position also, it can be concluded that the valve 13 of Figure 2 would only become pressed against the seal surface during an inhalation. A review of the '516 UK application thus leads me to believe that the valve shown in Figure 2 is a unidirectional exhalation valve that prevents the influx of contaminants through the exhalation valve during an inhalation when it is most needed. It is not apparent to me that

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the valve would be pressed towards the seal surface under a neutral condition when the wearer is neither inhaling nor exhaling.

Applicants have also reproduced paragraphs 15 and 16 of the Bowers' Declaration:

15. My review of the Simpson document reveals a flapper-style valve 13 in Fig. 2, which would not have its "flexible circular flap member 15" pressed against the valve's seal surface when a wearer of the mask is neither inhaling nor exhaling. The aligned relationship between the flap retaining surface and the seal surface and their relative positioning would not cause Simpson's flap 15 to be pressed against the valve's seal surface. At best the flap 15 would rest flush against the seal surface as a result of its securement at the flap retaining surface. The Simpson valve 13 therefore could allow for the influx of contaminants into the mask interior when, for example, a wearer tilts their head downwards and allows gravity to draw the flap away from the seal surface.

16. The Simpson product also has the valve located on the upper portion 1 of the pouch-shaped mask. This has the disadvantage that the warm moist exhaled air may be directed towards the eyes, causing misting of the eyewear. And Simpson's Fig. 2 valve cannot be positioned on the underside of the mask because the flap 15 would droop away from contact with the valve seat, causing the valve to leak.

As this testimony reveals, there is no mechanical means for having Simpson's flap 15 pressed against the seal surface. The Bowers' Declaration, in particular, states how the flap could droop away from the seal surface. It is improper for the Examiner to substitute his judgment for that of an expert in the field.<sup>1</sup> The Manual of Patent Examining Procedure explains:

Evidence traversing rejections must be considered by the Examiner whenever present. All entered affidavits, declarations, and other evidence traversing rejections are acknowledged and commented upon by the examiner in the next succeeding action....*Where the evidence is insufficient to overcome the rejection, the examiner must specifically explain why the evidence is insufficient.* General statements such as 'the declaration lacks technical validity' or 'the evidence is not commensurate with

<sup>1</sup> See, *In re Zeidler*, 215 USPQ 490 (CCPA 1982) ("Although perception of color may, in essence, be a 'subjective' determination, we believe that an expert's evaluation in this field is entitled to more weight than that of a layman. *In re Neave*, 34 CCPA 999, 1007, 370 F.2d 961, 968, 152 USPQ 274, 279-80 (1967) ("Therefore, because the qualifications of Lach and the test procedures which he employed are unchallenged, the board's holding that 'a more dramatic difference in results' is required constitutes reversible error, the board having erroneously substituted its judgment for that of an established expert in the art."); *In re Fay*, 146 USPQ 47 (CCPA 1965) ("It seems to us that one as well qualified in the highly technical art of fluoride-containing halogenated compounds as Henne is shown to be is properly entitled to express his expert opinion, and that such an opinion is entitled to be given consideration with the other evidence in the case in determining whether the conclusion of obviousness is supported by the opinion of the examiner as to what the prior art teaches. For the reasons previously stated we do not think the prior art teachings furnish factual support for the examiner's opinion."); see also *In re Allon*, 37 USPQ2d 1578 (Fed. Cir. 1996) ("We do, however, hold that the examiner's final rejection and Answer contained two errors; (1) viewing the Wall declaration as opinion evidence addressing a question of law rather than a question of fact; and (2) the summary dismissal of the declaration, without an adequate explanation of why the declaration failed to rebut the Board's *prima facie* case of inadequate description.").

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the scope of the claims' without an explanation supporting such findings are insufficient (emphasis added).<sup>2</sup>

Despite the explicit language in the MPEP highlighted above, the Examiner has yet to explain why the evidence furnished by applicants is insufficient. The Examiner only comments on what the Simpson patent does not disclose (and as indicated above, does so erroneously).

**3. Examiner's Answer at page 8, 1<sup>st</sup> partial paragraph**

"In order for the mask of Simpson et al. to function as it is intended (and there is no reason to even suspect that it does not), the exhalation valve (fig. 2) must remain closed until a wearer exhales; otherwise, gaseous or vaporous contaminants would leak into the interior of the mask body and be inhaled by such a wearer."

**Applicants' Response:**

Again, the Examiner is reviewing the Simpson patent from the perspective of the person who has read specification of applicants' invention rather than from the state-of-the-art that existed at the time the Simpson patent was published. The Examiner also ignores the actual disclosure in the Simpson patent. Simpson (i) does not impose a preload on its flapper valve 13 shown Figure 2, and Simpson (ii) places the valve 12 on the top portion 1 of the mask (figure 1) and (iii) suggests the use of an antechamber to prevent harmful contaminants from leaking into the mask through the exhalation valve (page 1, lines 58-63). For these three reasons, it is clear that the Simpson valve does not remain closed under any orientation of the mask. Thus, although it may be apparent that a person of ordinary skill would design a flapper valve that remained closed under all conditions after reading applicants' specification, it certainly was not apparent to Simpson in 1980. Further, the Simpson mask "does function as intended." It filters harmful components during an inhalation, and the Simpson valve purges exhaled air from the mask interior during an exhalation. The Simpson valve nonetheless does leak under other circumstances. Simpson explicitly admits this (p. 1, lines 58-63). Thus, the Examiner's position does not come from Simpson but rather is an unsupported viewpoint that was arrived at after reading applicants' specification.

<sup>2</sup> MANUAL OF PATENT EXAMINING Procedure § 2144.03, 2100-129 (August 2001).

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**4. Examiner's Answer at page 8, 1<sup>st</sup> full paragraph**

"Applicant is reminded that the language of each of claims 33 and 63 requires only that the valve be pressed towards the seal surface in an abutting relationship therewith when a fluid is not passing through the orifice."

**Applicants' Response:**

Applicants respectfully assert that this is not a proper construction of applicants' claims. Claims 33 and 63 both explicitly require that the flap be "pressed towards the seal surface in an abutting relationship therewith, *under any orientation of the valve*, when no external forces from the movement of fluid are exerted upon the flap". Simpson's valve does not show a flap 15 that can be pressed towards the seal surface under *any orientation of the valve* when no external forces from the movement of fluid are exerted upon the flap. The Examiner has completely ignored the italicized limitation of these claims. Failure to give consideration to this limitation is legal error.<sup>3</sup>

**5. Examiner's Answer at page 8, 1<sup>st</sup> full paragraph, second sentence**

"As discussed above with respect to claim 33, Simpson et al. teach such an arrangement during a wearer's inhalation period. That is, even if the valve flap (15) of Simpson et al. were to "droop" away from its seat during a period of time when a wearer is neither inhaling nor exhaling, there is at least A time period (i.e. inhalation) during which no fluid is flowing through orifice (16) simultaneous with the valve flap (15) being pressed in an abutting relationship with the valve seat."

**Applicants' Response:**

So what if there is a period of time when the Simpson valve might be pressed against the valve seat? Applicants do not claim a valve that is closed under only an inhalation. Applicants' claims state that their valve is "pressed towards the seal surface in an abutting relationship therewith, under any orientation of the valve, when no external forces from the movement of fluid are exerted upon the flap". The Simpson flap only remains pressed against the seal surface when a wearer inhales or from gravity when donned in an upright position; it does not do so under any orientation of the mask in the absence of external forces from the movement of fluid.

<sup>3</sup> *Glaxo v. Novopharm*, 110 F.3d 1562 (Fed. Cir. 1997) (It is elementary patent law that all limitations are material.).

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**6. Examiner's Answer at page 8, 2<sup>nd</sup> full paragraph**

"The Castiglione Affidavit is based upon the stated assertion (e.g. page 2, paragraph #9) that the valve flap (15) is not pressed into abutting relationship with the valve seat when a wearer is neither inhaling nor exhaling. While such may be the case, there is no objective evidence (e.g. a physical test of the mask disclosed by Simpson et al.) to support such a conclusion. Consequently, the affidavit is not persuasive."

**Applicants' Response:**

Applicants submit that the Examiner has again committed legal error by disregarding the testimony of an expert. There is no need for a physical test when an expert can readily ascertain the structural and functional relationship between the flap and the valve seat by viewing the drawings and reading the description. The Examiner has not demonstrated otherwise. Further, the burden is not upon applicants to produce a physical test when the record already establishes that Simpson's flap is not pressed towards the seal surface under any orientation of the valve. Even without the testimony of Castiglione and Bowers, it is apparent, simply from looking at Figure 2, that Simpson's flexible flap is not positioned on the flap seat such that it is pressed towards the seal surface in an abutting relationship with it under any orientation of the valve. Consequently, the affidavits could more properly be characterized as being "overkill" rather than being "not persuasive".

**7. Examiner's Answer at page 9, 1<sup>st</sup> paragraph**

"Applicant's arguments regarding the propriety of the combination of prior art to Simpson et al. and McKim are disagreed with. Inasmuch as the valve flap of McKim lifts from the valve seat responsive to the pressure of the fluid passing therethrough and reseats due to its resilience, it does exhibit flexibility."

**Applicants' Response:**

Any interpretation of McKim that would have its valve reed 14 qualify as a "flexible flap" would either be the result of an incorrect reading of the scope and content of McKim or an unreasonable interpretation of the term "flexible flap" in the present case. Applicants define the term "flexible" to mean that the flap can deform or bend in response to gravity or exhalation pressure. The record shows that McKim's valve reed 14 "of sheet material, such as, for example, shim stock" would not be able to bend in response to gravity or breath from a person. As such,

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the McKim reed valve would be inoperable in applicants' invention. And the function of it and its problems of operation in a 2-cycle engine cannot be so easily applied to the respiratory mask art. It is true that the McKim flap does exhibit "flexibility" under another construction of this term. Applicants, however, have not defined the term "flexible" to be so broad as to encompass shim stock that does not bend in response to the force of gravity or a wearer's exhalate. McKim may illustrate in its figs. 1 and 3 that its valve reed can be bent, but this bending is done in response to a strong external mechanical force. Thus, unless the Examiner can supply the record with evidence to demonstrate otherwise, it would appear that the Examiner is either improperly interpreting McKim or is giving an unreasonable interpretation of the meaning of the term "flexible flap".

**8. Examiner's Answer at paragraph bridging page 9, 1<sup>st</sup> paragraph, 3<sup>rd</sup> sentence**

"Applicant's arguments alleging that one of ordinary skill would not consult reed valves for high speed engines may be accurate; however, the fact that McKim teaches the mounting of a valve flap in a curved orientation for the expressed purpose of increasing the efficiency of the seal between the valve flap and valve seat is seen as relevant information to one of ordinary skill in the creation of a more efficient seal between a valve and seat in any environment including the environment of valves in the respiratory arts."

**Applicants' Response:**

McKim improves the efficiency of the seal by eliminating float or bounce, which occurs when a 2-cycle gasoline engine operates at high rpms. The record clearly establishes that float or bounce is not a problem that is encountered in the field of exhalation valves for filtering face masks. There is therefore no lack of efficiency that could stem from this problem. Thus, the "expressed purpose" that is cited by the Examiner as being "relevant information" for making the asserted combination simply is nonexistent in this record. The Examiner has accordingly committed legal error by using a fabricated reason for making the combination.

**9. Examiner's Answer at page 10, lines 5-7**

"Applicants' argument that the valve of McKim lacks the required flexibility of applicant's invention is disagreed with because McKim (figs. 1 and 3) illustrates flexibility of the valve flap (14)."



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Applicants' Response:

McKim may illustrate in its figs. 1 and 3 that its valve reed can be bent, but this illustration does not mean that the reed valve 14 in McKim qualifies as a "flexible flap" as that term would be reasonably interpreted by a person of ordinary skill, consistent with a reading of applicants' specification. As explained above, any interpretation of McKim, which would have its valve reed 14 qualify as a flexible flap, would either be the result of an incorrect reading of the scope and content of McKim or an overbroad unreasonable interpretation of the term "flexible flap". The record shows that McKim's valve reed 14 "of sheet material, such as, for example, shim stock" would not be able to be bent in response to gravity from the breath of a person.<sup>4</sup> Unless the Examiner can supply the record with evidence to demonstrate otherwise, the Examiner must be giving an unreasonable construction to the meaning of "flexible flap".

10. Examiner's Answer at page 10, lines 7-10

"Further, the manner of bending illustrated in figs. 1 and 3 of McKim is consistent with appellants definition of a '...the flap can form or bend in the form of a self-supporting arc when secured at one end as a cantilever and view from a side elevation...'"

Applicants' Response:

The Examiner is again factually misrepresenting the record. The manner of bending McKim's metal valve reed is not consistent with applicants' definition. Applicants' invention uses flexible flaps that can deform or bend in response to gravity or pressure from a person's exhaled breath. McKim clearly uses a mechanical means to cause its valve reed 14 to be bent. The force that McKim uses, as described by Betts, is on orders of magnitude greater than the forces that are used to bend flexible flaps in exhalation valves. If the McKim valve could bend so easily, its 2-cycle engine would be inoperative. When the meaning of applicants' term "flexible flap" is given an interpretation that is not just the broadest construction possible but is instead the broadest *reasonable* interpretation, *consistent* with the specification, as required by law, there can be no other conclusion other than that McKim's valve reed 14 would not qualify as a flexible flap.

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<sup>4</sup> See Richard Betts' Declaration.

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**11. Examiner's Answer at page 10, lines 10-12**

"Finally, no particular degree of flexibility is quantitatively and/or structurally defined in any manner which is unobvious over the prior art combination of Simpson et al. as modified by McKim."

**Applicants' Response:**

Applicants have defined the term flexible to mean that the flap can "deform or bend in the form of a self-supporting arc when secured at one end as a cantilever and viewed from a side elevation" (p. 7, lines 22-24). Thus, it is incorrect to say that no degree of flexibility is quantitatively defined. As the Board is aware, claims must be interpreted in light of the specification and definitions set forth therein. Claims are not given simply the broadest construction possible but rather the broadest reasonable interpretation consistent with the specification.<sup>5</sup>

McKim clearly uses a mechanical means to cause its valve reed 14 to be bent. The force that McKim uses, as described by Betts, is on orders of magnitude greater than the forces that are used to bend flexible flaps in exhalation valves. If the McKim valve could bend so easily, its 2-cycle engine would be inoperative. When the meaning of applicants' term "flexible flap" is given an interpretation that is not just the broadest construction possible but instead is the broadest *reasonable* interpretation, *consistent* with the specification, as required by law, there can be no other conclusion other than that McKim's valve reed 14 would not qualify as a flexible flap.

**12. Examiner's Answer at page 11, 2<sup>nd</sup> full paragraph**

"Applicants' assertion that the Examiner has not provided any teaching, suggestion or motivation to combine the prior art to Simpson et al. and McKim is not accurate. As set forth in the body of the rejection, the reason for combination of Simpson et al. with McKim is because it would have provided for quick effective seating without float or bounce after each opening as taught by McKim (col. 1, lines 64-72)."

<sup>5</sup> *In re Reuter*, 651 F.2d 751, 210 USPQ 249, 253 (CCPA 1981); *In re Sneed*, 710 F.2d 1544, 218 USPQ 385, 388 (Fed. Cir. 1983).

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**Applicants' Response:**

The Examiner's position confuses unsupported opinion with evidence. As applicants have demonstrated repeatedly in this prosecution, persons skilled in the art of designing exhalation valve's do not search for solutions to eliminating float or bounce. Applicants have supported this position with uncontroverted documentary evidence in the form of Affidavits and Declarations signed by persons skilled in the field of designing such valves. The record also is devoid of a single reference that states, either explicitly or implicitly, that exhalation valves exhibit float or bounce problems. Because applicants have fully established that persons who design exhalation valves do not encounter — much less look for solutions to — "float or bounce" problems, the record accordingly lacks any motivating evidence for making the combination asserted in the rejection. Nonetheless, the Examiner maintains the position that a person skilled in the art of designing exhalation valves would have used the teachings of McKim's gasoline engine reed valve for purposes of eliminating float or bounce in an exhalation valve despite no evidentiary authority in the record, other than mere opinion.<sup>6</sup> As the Board is aware, bald conclusions like this are not *evidence* that can be properly relied on to sustain a rejection based on a combination of references.<sup>7</sup>

**13. Examiner's Answer at paragraph bridging pages 10 and 11**

"Applicants' assertion that Simpson et al. and McKim each present very good evidence of a lack of motivation to combine their respective teachings because no one of ordinary skill in the respirator art has made use of the teachings of McKim in making an exhalation valve is not accurate because examples of the use of the manner of mounting valves as taught by McKim do exist in the respirator art. The mounting of flapper valves in the respirator art by clamping a stationary portion of the flap in a different plane than the sealing surface (i.e. seat) resulting in a curved configuration which physically biases a free end of the valve to a closed position is well

<sup>6</sup> "Unsupported" is probably not the best word to use in this sentence. The Examiner's view is not merely "unsupported": it is actually "false". This falsity has been established by Bowers and Fabin when they unequivocally stated that float or bounce is not a problem that is confronted by persons who design exhalation valves.

<sup>7</sup> See, *In re Dembiczak*, 50 USPQ 1614, 1617 (Fed. Cir. 1999) ("Broad conclusory statements regarding the teachings of multiple references, standing alone, are not 'evidence.'"); See also, *Lee*, 61 USPQ2d at 1434 ("With respect to Lee's application, neither the examiner nor the Board adequately supported the selection and combination of the Nortrup and Thunderchopper references to render obvious that which Lee described. The examiner's conclusory statements that 'the demonstration mode is just a programmable feature which can be used in many different device[s] for providing automatic introduction by adding the proper programming software' and that 'another motivation' would be that the automatic demonstration mode is user friendly and it functions as a 'tutorial' do

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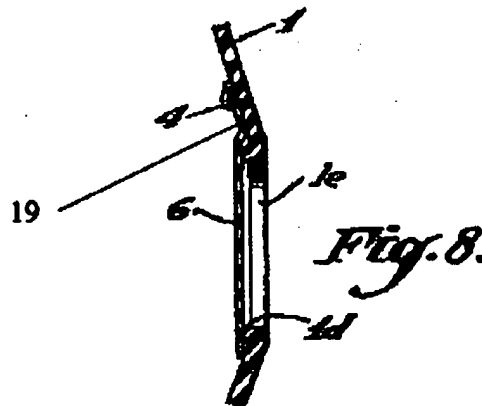
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known (see fig. 3 of Simpson et al.). Another example is seen in the prior art to Matheson (cited but not applied) U.S. Patent 2,999,498, fig. 8 and col. 1, lines 38-46.

**Applicants Response:**

The Examiner's position is inaccurate: the scope and content of the prior art have again been mischaracterized. Simpson does not disclose a flapper valve in its fig. 3. Figure 3 illustrates a button-style valve. Additionally, the mounting surface of the Simpson fig. 3 valve resides in the same plane as the sealing surface. Thus, there is no bias on the flap in any event.

The prior art to Matheson (U.S. 2,999,498) describes an inhalation valve, not an exhalation valve. And there is no disclosure in Matheson, which disclosure shows that its flap is biased towards the seal surface. In fact, Matheson teaches the opposite. Figure 8 of Matheson is reproduced below for ease of reference.



As shown, the Matheson valve has a "kink" in it at the location identified by applicants' attorney using numeral 19. This "kinked" portion would not cause the free portion of the flap to be pressed towards the seal surface so that it may reside closed under any orientation of the valve. Indeed, Matheson realizes this by indicating that its valve requires gravity to keep the flap closed:

An important feature of suspending diaphragms 6 and 7 from the top only without further support along the marginal portions is that gravity will assist in keeping the diaphragms in their normal downward and seated positions as shown in Fig. 8.<sup>8</sup>

not adequately address the issue of motivation to combine. The factual question of motivation is material to patentability, and could not be resolved on subjective belief and unknown authority.").

<sup>8</sup> See the '498 patent to Matheson at column 2, lines 53-57.

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Further, inhalation valves, unlike exhalation valves, close during an exhalation in response to the exhalation pressure. And air that passes through the inhalation valve must first pass through the filtration media in the filter cartridge. Therefore, there is no need to place a pre-stress on the valve to keep it closed under any orientation of the mask. The inhalation valve closes forcibly when a wearer exhales (see the '498 patent to Matheson at column 4, lines 1-8) so that the exhaled air is quickly forced out of the exhalation valve save rather than through the filtration media.

**14. Examiner's Answer at page 14, 2<sup>nd</sup> full paragraph**

"Finally, the question of whether McKim constitutes non-analogous art has been addressed and settled in a previous appeal to the Board of Appeals in appellants' related application 08/240,877 in which the Board of Appeals upheld the prior art combination of McKim with other prior art references including Simpson et al."

**Applicants' Response:**

Once again the Examiner has mischaracterized the record. The Board of Patent Appeals and Interferences has never dealt with the issue of whether McKim constitutes non-analogous art. That issue was never raised in application 08/240,877. Therefore, it was never decided. Applicants never argued that McKim was non-analogous art, and the Board made no reference to the issue in their decision. Further, the claims that were present in 08/240,877 are distinctly different from the claims that are present on appeal in this case. In addition, the evidence presented in the Castiglione, Bowers, Fabin, and Betts' Declarations was not of record in the '877 case. In short, the issue was never presented, never decided, and even if it was, it would not be pertinent to the present case because the claims are different and additional evidence is now of record.

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For the reasons submitted above and those presented in their Appeal Brief, applicants believe that the decision below should be reversed.

Respectfully submitted,

December 3, 2003

Date

By: 

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Application No.: 09/678579

First Named Inventor: Japuntich, Daniel A.

Title: FIBROUS FILTRATION FACE MASK HAVING A NEW UNIDIRECTIONAL FLUID VALVE

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Attachments: Reply Brief in triplicate

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